



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,543	07/27/2001	Konrad Basler	Q-60361	9256

7590 04/04/2005

SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/915,543

Applicant(s)

BASLER ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☒ Newly proposed or amended claim(s) 71,73,75 and 77 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 71,73,75 and 77.
Claim(s) objected to: _____.
Claim(s) rejected: 79-82 for the reasons of record set forth in the prior Office Action mailed 11-30-2004.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached document setting for the Examiner's response to Applicant's arguments.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/Q8 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.


ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit: 1635

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 71, 73, 75, and 77 under 35 USC 102(e) over Tang et al., and the rejection of claims 71, 73, 75 and 77 under 35 USC 112, 1st paragraph, were withdrawn in response to Applicant's amendment filed 2-28-05.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 79-81 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

Applicant's arguments filed 2-28-05 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the Examiner's rejection is improper, since it is not the function of the claims to exclude inoperative embodiments, but rather the function of claims is to recite the invention. The invention is the recited domains and polypeptides containing the same, but not polypeptides containing both domains, and which inhibits tcf-driving luciferase activity. Moreover, Applicants argue that it is not required that either the specification or the claims recite what additional amino acids can be added and still give rise to functional polypeptides, since such can be determined by routine experimentation. According to Applicants, the claims must merely recite the critical elements of the invention, and as the additional sequences which may or may not be present are not critical to the invention (as long as both the domains are not present at the same time), Applicants respectfully submitted that it is improper for the Examiner to require Applicants to further limit the claims. Moreover, Applicants contend that the specification does disclose structural/functional relationship between

Art Unit: 1635

the claimed residues and tcf-driven luciferase activity, as demonstrated in the Examples of the present specification.

Applicant's arguments do not take the place of evidence that the specification as originally filed, describes the full scope of the instantly claimed invention. According to Applicants, a correlation between the ability of claimed polypeptides to inhibit tcf-driven luciferase activity in colon cancer cells, and the structure of the claimed polypeptides has been established by the description of the amino acids 177 to 204, and amino acids 349 to 383 of SEQ ID NO: 15, and their ability to bind either Doll or β -Cat. The Examiner agrees with Applicants with this particular aspect of the invention. However, there is no guidance, support, or description in the specification as filed for peptides having at least 90% amino acid sequence identity to a peptide consisting of amino acids 177 to 204 or 349 to 383 of SEQ ID NO: 15, wherein said polypeptides maintain the ability to bind either Doll or β -Cat, and further inhibit tcf-driven luciferase activity in colon cancer cells. It is clear that in order to properly define the full scope of polypeptides according to claims 79-82 which possess the claimed functional activity, further experimentation is required. According to Applicants, it is not required that either the specification or the claims recite what additional amino acids can be added and still give rise to functional polypeptides, since such can be determined by routine experimentation. However, contrary to Applicant's assertions an invention is not considered adequately described if the description is dependent upon further experimentation. According to MPEP § 2163, "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by

Art Unit: 1635

a method of obtaining the claimed sequence.” Moreover, see the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, “Written Description” Requirement. These guidelines state: “[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.” Since Applicants assert that further experimentation is necessary to permit the isolation of the full scope of polypeptides encompassed by the instant claims, it is clear that per MPEP § 2163 and the excerpt from the Written Description Guidelines (1999) cited above, the full scope of polypeptides encompassed by the instant claims was not reduced to practice or “ready for patenting” as of the filing date of the instant invention. The specification has provided written description for the specific sequences recited in the claims, however, there is not sufficient written description to determine which polypeptides comprising these sequences or comprising peptides with 90% identity to these sequences meet the functional limitations.

Art Unit: 1635

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1635

JLE